



PTO/SB/08A (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 10

Complete if Known

Application Number	10/781,173
Filing Date	February 18, 2004
First Named Inventor	Rodriguez
Art Unit	1614
Examiner Name	Shirley V. Gembeh
Attorney Docket Number	31140C

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
SG		US- 5,190,935	03-02-1993	Binderup	
		US- 5,206,229	04-27-1993	Calverley	
		US- 5,246,925	09-21-1993	Deluca	
		US- 5,278,155	01-11-1994	Ikekawa	
		US- 5,373,004	12-13-1994	Deluca	
		US- 5,374,629	12-20-1994	Calverley	
		US- 5,380,720	01-10-1995	Deluca	
		US- 5,387,582	02-07-1995	Hansen	
		US- 5,389,622	02-14-1995	Posner	
		US- 5,401,731	03-28-1995	Calverley	
		US- 5,411,949	05-02-1995	Neef	
		US- 5,428,029	06-27-1995	Doran	
		US- 5,446,035	08-29-1995	Neef	
		US- 5,451,574	09-19-1995	Baggiolini	
		US- 5,484,782	01-16-1996	Deluca	
		US- 5,512,554	04-30-1996	Baggiolini	
		US- 5,532,228	07-02-1996	Neef	
		US- 5,536,713	07-16-1996	Deluca	
		US- 5,554,599	09-10-1996	Grue-Sorenson	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code* ³ -Number* ⁴ -Kind Code* ⁵ (if known)	MM-DD-YYYY			
SG		WO 97/11680	04-03-1997	Elliesen		
SG		WO 98/10771 A1	03-19-1998	Rodriguez		
SG		WO 98/56389	12-17-1998	Rodriguez		

Examiner
Signature

/Shirley Gembeh/

Date
Considered

01/22/2007

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet **2** of **10****Complete if Known**

Application Number	10/781,173
Filing Date	February 18, 2004
First Named Inventor	Rodriguez
Art Unit	1614
Examiner Name	Shirley V. Gembeh
Attorney Docket Number	31140C

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
SG		US- 5,716,945	02-10-1998	Grue-Sorensen	
		US- 6,028,064	02-22-2000	Rodriguez	
		US- 6,034,074	03-07-2000	Rodriguez	
		US- 6,310,054	10-30-2001	Rodriguez	
		US- 6,319,911	11-20-2001	Rodriguez	
		US- 6,407,082	06-18-2002	Rodriguez	
		US- 6,444,658	09-03-2002	Rodriguez	
		US- 6,511,970	01-28-2003	Rodriguez	
		US- 6,521,608	02-18-2003	Henner	
		US- 6,765,002	07-20-2004	Rodriguez	
		US- 6,977,250	12-20-2005	Rodriguez	
		US- 7,053,074	05-30-2006	Rodriguez	
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ² -Number ³ -Kind Code ⁴ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁵

Examiner Signature	/Shirley Gembeh/	Date Considered	01/22/2007
--------------------	------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/781,173
		Filing Date	February 18, 2004
		First Named Inventor	Rodriguez
		Art Unit	1614
		Examiner Name	Shirley V. Gembeh
Sheet 3	of 10	Attorney Docket Number	31140C

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SG		BECHTEL, Limitations of pulse oral calcitriol therapy in continuous ambulatory peritoneal dialysis patients, American Journal of Kidney Disease, Feb. 1995, 291-296, 25:2	
		BECKMAN, In vivo regulation of rat intestinal 24-hydroxylase: potential new role of calcitonin, Endocrinology, 1994, 1951-1955, 135:5	
		BEER, A phase I trial of pulse calcitriol in patients with refractory malignancies pulse dosing permits substantial dose escalation, Cancer, June 2001, 2431-2439, 91:12	
		BEER, Beer Abstract, 2002	
		BOWER, Topical calcipotriol treatment in advanced breast cancer, The Lancet, March 2001, 701-702, 337	
		BRAZEROL, Serial ultraviolet B exposure and serum 25 hydroxyvitamin D response in young adult american blacks and whites: no racial differences,	
		(cont.) Journal of American College of Nutrition, 1988, 111-118, 7:2	
		BRENNER, Cyclic changes in the primate oviduct and endometrium, Knobil E. Neill JD. eds. The Physiology of Reproduction, 1994, 541-569, 2nd Ed.	
SG		BUCHANAN, The effect of endogenous estrogen fluctuation on metabolism of 25-hydroxyvitamin D, Calcified Tissue International, 1986, 139-144, 39	
		BURAS, Vitamin D receptors in breast cancer cells, Breast Cancer Research and Treatment, 1994, 191-202, 31	

Examiner Signature	/Shirley Gembeh/	Date Considered	01/22/2007
--------------------	------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/781,173
Filing Date	February 18, 2004
First Named Inventor	Rodriguez
Art Unit	1614
Examiner Name	Shirley V. Gembeh
Attorney Docket Number	31140C

Sheet

4

of

10

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SG		CARRINO, Proteoglycan synthesis in vitamin D-Deficient Cartilage: Recovery from vitamin D deficiency, Connective Tissue Research, 1989, 135-147, 19	
		CHAPUY, Effect of calcium and cholecalciferol treatment for three years on hip fractures in elderly women, BMJ, April 1984, 1081-1082, 308	
		CHIDA, Inhibition of tumor in mouse skin by 1 α , 25-dihydroxyvitamin D ₃ , 1985, Cancer Research, 5426-5430, 45	
		CHRISTAKOS, Vitamin D and Breast Cancer, Diet and Breast Cancer, 1994, 115-118, 12	
		CHRISTOPHERSON, Responsiveness of human carcinoma cells of gynecologic origin to 1,25 dihydroxycholecalciferol, Am. J. Obstet. Gynecol., 1986, 1293-1296, 155:6	
		COHEN, Apoptosis, Immunology Today, 1993, 126-130, 14:3	
		COLLINS, A prospective study to evaluate the dose of vitamin D required to correct low 25-hydroxyvitamin D levels, calcium, and alkaline phosphatase in patients at risk of	
		(cont.) developing antiepileptic drug-induced osteomalacia, Quarterly Journal of Medicine, 1991, 113-122, 78:286	
		COLSTON, 1,25-Dihydroxyvitamin D ₃ and malignant melanoma: The presence of receptors and inhibition of cell growth in culture, Endocrinology, 1981, 1083-1086, 108	
SG		COOPER, Olestra dose response on fat-soluble and water-soluble nutrients in the pig, American Society for Nutritional Sciences, 1997, 1573S-1588S	

Examiner Signature	/Shirley Gembeh/	Date Considered	01/22/2007
--------------------	------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/781,173
Filing Date	February 18, 2004
First Named Inventor	Rodriguez
Art Unit	1614
Examiner Name	Shirley V. Gembeh
Attorney Docket Number	31140C

Sheet

5

of

10

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SG		COOPER, Olestera's effect on the status of vitamins A, D and E in the pig can be offset by increasing dietary levels of these vitamins,	
		(cont.) American Society for Nutritional Sciences, 1997, 1589S-1607S	
		CORDER, Vitamin D and prostate cancer: A prediagnostic study with stored sera, Cancer Epidemiology Biomarkers & Prevention, 1993, 467-472, 2	
		DAVIE, Vitamin D from skin: contribution to vitamin D status compared with oral vitamin D in normal and anticonvulsant-treated subjects, Clinical Sciences, 1982, 461-472, 63	
		DAVOODI, Modulation of vitamin D receptor by 1,25 (OH) ₂ -Vitamin D ₃ in t-47D human breast cancer cells, J. Steroid Biochem. Molec. Biol., 1995, 147-153, 54(3/4)	
		DODD, Vitamin D metabolites change the phenotype of monoblastic U937 cells, Proc. Natl. Acad. Sci., USA, 1983, 7538-7541, 80	
		DOKOH, Influence of 1,25-dihydroxyvitamin D ₃ on cultured osteogenic sarcoma cells: correlation with the 1,25-dihydroxyvitamin D ₃ receptor, Cancer Research, 1984, 2103-09, 44	
		EISMAN, Suppression of in vivo growth of human cancer solid tumor xenografts by 1,25-dihydroxyvitamin D ₃ , Cancer Research, 1987, 21-25, 47	
↓		FRAMPTON, Inhibition of human cancer cell growth by 1,25-dihydroxyvitamin D ₃ Metabolites, Cancer Research, 1983, 4443-4447, 43	
SG		GABORIT, Osteoporose et prise prolongee D'antialdosterone, Revue du Rhumatisme, 1983, 535-539, 50:7	

Examiner Signature	/Shirley Gembeh/	Date Considered	01/22/2007
--------------------	------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/781,173
		Filing Date	February 18, 2004
		First Named Inventor	Rodriguez
		Art Unit	1614
		Examiner Name	Shirley V. Gembeh
Sheet 6	of 10	Attorney Docket Number 31140C	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SG		GAO, The effects of chemotherapy including cisplatin on vitamin D metabolism, Endocrine Journal, 1993, 737-742, 40:6	
		GARCIA-DELGADO, Calcitonin, etidronate, and calcidiol treatment in bone loss after cardiac transplantation, Calcified Tissue International, 1997, 155-159, 60	
		GRECU, Effects of medroxyprogesterone acetate on some parameters of calcium metabolism in patients with glucocorticoid-induced osteoporosis, Bone and Mineral, 1991, 153-61, 13	
		GULLIFORD, A phase I study of the vitamin D analogue EB 1089 in patients with advanced breast and colorectal cancer, British Journal of Cancer, 1998, 6-13	
		HEIKINHEIMO, Annual Injection of Vitamin D and fractures of aged bones, Calcified Tissue International, 1992, 105-110, 51	
		HILLMAN, Absorption, dosage, and effect on mineral homeostasis of 25-hydroxycholecalciferol in premature infants: Comparison with 400 and 800 IU vitamin D2 supplementation,	
		(cont.) The Journal of Pediatrics, 1984, 981-989	
		HOLICK, Evolutionary biology and pathology of vitamin D, Symposium Vitamin D, 1990, 79-83, 2	
		KIRKEMO, Serum vitamin level maintenance in cancer patients on total parenteral nutrition, The American Journal of Clinical Nutrition, 1982, 1003-1009	
SG		LAWSON, Interrelationships in rats of tissue pools of cholecalciferol and 25-hydroxycholecalciferol formed in u.v. light, Biochem, 1986, 535-540, 233	

Examiner Signature	/Shirley Gembeh/	Date Considered	01/22/2007
--------------------	------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/781,173
Filing Date	February 18, 2004
First Named Inventor	Rodriguez
Art Unit	1614
Examiner Name	Shirley V. Gembeh
Attorney Docket Number	31140C

Sheet

7

of

10

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SG		LEFKOWITZ, Sunlight, Vitamin D, and ovarian cancer mortality rates in U. S. women, International Journal of Epidemiology, 1994, 1133-1136, 23:6	
		LEGER, Prophylaxie de la carence en vitamine D chez le nouveau-ne hypotheiroidien, Arch Fr Pediatr., 1989, 567-71, 46	
		MALLET, Vitamin D supplementation in pregnancy: A controlled trial of two methods, Obstetrics & Gynecology, 1986, 300-304, 68:3	
		MANGELSDORF, 1,25-dihydroxyvitamin D3-induced differentiation in a human promyelocytic leukemia cell line (HL-60): Receptor mediated maturation to macrophage-like cells,	
		(cont.) J. Cell. Biol., 1984, 391-398, 98	
		MATHIASSEN, EB 1089, A novel vitamin D analogue has strong antiproliferative and differentiation inducing effects on cancer cells, J. Steroid Biochem. Molec. Biol. 1993, 365-371	
		MOORE, Differentiating effects of 1,25-dihydroxycholecalciferol (D3) on La-N-5 human neuroblastoma cells and its synergy with retinoic acid, Journal of Pediatric Hematology/	
		(cont.) Oncology, 1995, 311-317, 17:4	
		NARANG, Role of Vitamin D in pulmonary tuberculosis, The Journal of the Association of Physicians of India, 1984, 185-188, 32:2	
SG		NARVAEZ, Characterization of a vitamin D3-resistant MCF-7 cell line, Endocrinology, 1996, 400-409, 137:2	

Examiner
Signature

/Shirley Gembeh/

Date
Considered

01/22/2007

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/781,173
Filing Date	February 18, 2004
First Named Inventor	Rodriguez
Art Unit	1614
Examiner Name	Shirley V. Gembeh
Attorney Docket Number	31140C

Sheet

8

of

10

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SG		NEED, Comparison of calcium, calcitrol, ovarian hormones and nandrolone in the treatment of osteoporosis, Maturitas, 1986, 275-280, 8	
		NIEVES, High prevalence of vitamin D deficiency and reduced bone mass in multiple sclerosis, Neurology, 1994, 1687-1692, 44	
		ROBERTS, Serial changes in serum vitamin K1, triglyceride cholesterol, osteocalcin and 25-hydroxyvitamin D3 in patients after hip replacement for fractured neck of femur or	
		(cont.) Osteoarthritis, European Journal of Clinical Investigation, 1996, 24-29, 26	
		SANCHEZ-CABEZUDO, Effect of oral calcidiol treatment on its serum levels and peritoneal losses, International Society for Peritoneal Dialysis, 1995, 65-70, 15	
		SATO, Antitumor effect of 1a-hydroxyvitamin D3, Tohoku J. Exp. Med., 1982, 445-446, 138	
		SAUNDERS, Repression of c-myc expression in ovarian carcinoma cells by 1,25-dihydroxyvitamin D3, Twenty-Third Annual Meeting of the Society of Gynecologic	
		(cont.) Oncologists, March 15-18, 1992. Gynecol. Oncol., 1992, 83-84, 45:1	
↓		SAUNDERS, Receptors for 1,25-dihydroxyvitamin D3 in gynecologic neoplasms, Gynecologic Oncology, 1992, 131-136, 44:2	
SG		SAUNDERS, Inhibition of c-myc in breast and ovarian carcinoma cells by 1,25-dihydroxyvitamin D3, retinoic acid and dexamethasone, Anti-Cancer Drugs, 1993, 201-208: 4:2	

Examiner Signature	/Shirley Gembeh/	Date Considered	01/22/2007
-----------------------	------------------	--------------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/781,173
		Filing Date	February 18, 2004
		First Named Inventor	Rodriguez
		Art Unit	1614
		Examiner Name	Shirley V. Gembeh
Sheet 9	of 10	Attorney Docket Number	31140C

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SG		SAUNDERS, Inhibition of breast and ovarian carcinoma cells growth by 1,25-dihydroxyvitamin D3, combined with retinoic acid and dexamethasone, Anti-Cancer Drugs, 1995, 562-69	
		SAUNDERS, Additive inhibition of RL95-2 endometrial carcinoma cell growth by carboplatin and 1,25-dihydroxyvitamin D3, Gynecologic Oncology, 1993, 155-159, 51	
		SCRAGG, Plasma 25-hydroxyvitamin D3 and its relation to physical activity and other heart disease risk factors in the general population, Epidemiology, 1992, 697-703, 5:2	
		SHABAHANG, 1-25 dihydroxyvitamin D3 receptor as a marker of human colon carcinoma cell line differentiation and growth inhibition, Cancer Research, 1993, 3712-3718, 53	
		SMITH, A phase I trial of calcitriol (1,25-dihydroxycholecalciferol) in patients with advanced malignancy, Clinical Cancer Research, 1999, 1339-1345, 5	
		SPORN, Prevention of carcinogenesis with vitamin D analogs, Proceedings American Association for Cancer Research, 1993, 622, 34	
		STUDZINSKI, Sunlight-can it prevent as well as cause cancer? Cancer Research, 1995, 4014-4022, 55	
		TRIVEDI, Effect of four monthly oral vitamin D3 (cholecalciferol) supplementation on fractures and mortality in men and women living in the community: randomised double blind	
		(cont.) controlled trial, BMJ, 2003, 1-6, 326	
SG		TSUKAMOTO, The oral 1,25-dihydroxyvitamin D3 pulse therapy in hemodialysis patients with severe secondary hyperparathyroidism, Nephron, 1991, 23-28	

Examiner Signature	/Shirley Gembeh/	Date Considered	01/22/2007
--------------------	------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/781,173
Filing Date	February 18, 2004
First Named Inventor	Rodriguez
Art Unit	1614
Examiner Name	Shirley V. Gembeh
Attorney Docket Number	31140C

Sheet 10

of

10

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SG		VINK-VAN WIJNGAARDEN, Inhibition of breast cancer cell growth by combined treatment with vitamin D3 analogues and tamoxifen, Cancer Research, 1994, 5711-5717, 54	
		WELSH, Induction of apoptosis in breast cancer cells in response to vitamin D and antiestrogens, Biochem. Cell. Biol., 1994, 537-545, 72	
		YOSHIDA, Conservative treatment of refractory myelodysplastic anemias: A Japanese cooperative study, ACTA Haematologica Japonica, 1988, 1448-1454, 51	
		ZEGHOUD, Vitamin D prophylaxis during infancy: comparison of the long-term effects of three intermittent doses (15, 5, or 2.5 mg) on 25-hydroxyvitamin D concentrations,	
		(cont.) Am. J. Clin. Nutr., 1994, 393-396, 60	
SG		U.S. Patent Application Ser. No. 11/441,877, filed on May 26, 2006 (Inventor: Roidriguez, et al.)	

Examiner Signature	/Shirley Gembeh/	Date Considered	01/22/2007
--------------------	------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.